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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,433	10/01/2003	Arpi Matossian-Rogers	2003_1279	5502

513 7590 11/17/2005

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EXAMINER	
HADDAD, MAHER M	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 11/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/674,433	MATOSSIAN-ROGERS, ARPI	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 January 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,12,14,15 and 17-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-10, 12, 14-15, 17-29* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-10, 12, 14-15 and 17-29 are pending.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-10, drawn to a monoclonal or polyclonal antibody with reactivity against an anti-TCR Vβ antibody for use as a pharmaceutical or as a diagnostic agent, classified in Class 530, subclass 387.2.

II. Claims 1-10, drawn to a ligand with reactivity against an anti-TCR Vβ antibody for use as a pharmaceutical or as a diagnostic agent, classified in Class 530, subclasses 324-330 and 350.

III. Claim 12, drawn to a peptide, oligopeptide, polypeptide or protein that bound by a monoclonal or polyclonal antibody with reactivity against an anti-TCR Vβ antibody, which is not an anti-TCT Vβ antibody; classified in Class 530, subclasses 324-330 and 350.

IV. Claims 14 and 15, drawn to a peptide, oligopeptide, polypeptide or protein comprising the sequence of ESRP1; classified in Class 530, subclasses 324-330 and 350.

V. Claim 17, drawn to a cDNA, RNA or genomic DNA sequence encoding a monoclonal or polyclonal antibody with reactivity against an anti-TCR Vβ antibody; classified in Class 536, subclass 23.5.

VI. Claim 17, drawn to a cDNA, RNA or genomic DNA sequence encoding a ligand with reactivity against an anti-TCR Vβ antibody; classified in Class 536, subclass 23.5.

VII. Claim 17, drawn to a cDNA, RNA or genomic DNA sequence encoding a peptide, oligopeptide, polypeptide or protein that is bound by a mounoclonal or polyclonal antibody or equivalent ligand with reactivity against an anti-TCR Vβ antibody, which is not an anti-TCR Vβ antibody; classified in Class 536, subclass 23.5.

VIII. Claims 18-22, drawn to a cDNA, RNA, or genomic DNA sequence encoding ESRP1, vectors, bacteriophage clones, host cells, classified in Class 536, subclass 23.5; Class 435, subclasses 69.1, 455, 252.3, and 320.1.

IX. Claims 23-28, drawn to a method for detection of a naturally-occurring autoantibody comprising contacting a sample with a monoclonal or polyclonal antibody with reactivity against an anti-TCR Vβ antibody, classified in Class 435, subclass 7.1.

X. Claims 23-28, drawn to a method for detection of a naturally-occurring autoantibody comprising contacting a sample with a ligand with reactivity against an anti-TCR Vβ antibody, classified in Class 435, subclass 7.1.

XI. Claims 29, drawn to method of treatment of an autoimmune disease comprising administering to a patient an effective amount of *the antibody* with reactivity against an anti-TCR Vβ antibody, classified in Class 424, subclass 131.1.

XII. Claims 29, drawn to method of treatment of a cardiovascular disease comprising administering to a patient an effective amount of *the antibody* with reactivity against an anti-TCR Vβ antibody, classified in Class 424, subclass 131.1.

XIII. Claims 29, drawn to method of treatment of cancer comprising administering to a patient an effective amount of *the antibody* with reactivity against an anti-TCR Vβ antibody, classified in Class 424, subclass 131.1.

XIV. Claims 29, drawn to method of treatment of other suitable disease comprising administering to a patient an effective amount of *the antibody* with reactivity against an anti-TCR Vβ antibody, classified in Class 424, subclass 131.1.

XV. Claim 29, drawn to method of treatment of an autoimmune disease comprising administering to a patient an effective amount of an equivalent ligand with reactivity against an anti-TCR Vβ antibody, classified in Class 424, subclass 185.1.

XVI. Claim 29, drawn to method of treatment of a cardiovascular disease comprising administering to a patient an effective amount of an equivalent ligand with reactivity against an anti-TCR Vβ antibody, classified in Class 424, subclass 185.1.

XVII. Claim 29, drawn to method of treatment of cancer comprising administering to a patient an effective amount of an equivalent ligand with reactivity against an anti-TCR Vβ antibody, classified in Class 424, subclass 185.1.

XVIII. Claim 29, drawn to method of treatment of other suitable disease comprising administering to a patient an effective amount of an equivalent ligand with reactivity against an anti-TCR Vβ antibody, classified in Class 424, subclass 185.1.

3. Groups I-VIII are different products. Nucleic acids, polypeptides, and antibodies differ with respect to their structures and physicochemical properties; therefore each product is patentably distinct.

4. Groups IX-XVIII are different methods. Various methods of detecting and various methods of treating differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

5. Groups I/(IX and XI-XIV) and II/(X and XV-XVIII) are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group I and the ligand of Group II can be used for affinity purification, in addition to the various methods of treating and detecting recited.

6. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper. Further, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention.

Species Election

7. Irrespective of whichever group applicant may elect, applicant is further required under 35 US 121 (1) to elect a single disclosed species to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

A. If any one of Groups XI or XV is elected, applicant is required to elect a single specific autoimmune disease such a) IDDM, b) NIDDM, c) organ specific or d) non-organ specific autoimmune disease. These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

8. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the

election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

9. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

10. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

November 11, 2005

Maher Haddad

Maher Haddad, Ph.D.
Patent Examiner
Technology Center 1600